REMARKS

Claims 1-29 are pending in the subject application and are subject to a restriction requirement.

Requirement for restriction under 35 U.S.C. 121

In the August 4, 2004 Office Action, the Office required restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

Group I	Claims 2-6, 13, 15, 19-21 are drawn to a method of aiding in the diagnosis of the neoplastic conditions, classified in class 435, subclass 6.
Group II	Claims 8-12, 16-18, drawn to a method of aiding in the diagnosis of the neoplastic conditions, classified in class 435, subclass 7.23.
Group III	Claims 22-26, drawn to a diagnostic kit comprising at least one agent that binds to eIF3 protein, classified in class 530, subclass 387.1.
Group IV	Claim 27, drawn to diagnostic kit comprising primer, classified in class 530, subclass 24.33.
Group V	Claims 28 and 29, drawn to an assay to screen for agents that modulates eIF3 protein, classified in class 435, subclass 7.1

The Office states that claims 1, 7 and 14 link the inventions of Group I and Group II and that the instant restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. The Office states that Groups I and II contain claims generic to a plurality of patentably distinct species.

In Group I there are two genuses with multiple species:

Genus 1:	ovary, breast, prostate, lung, pancreas, gastrointestine, and blood.
Genus 2:	SEQ ID NO:1, SEQ ID NO:12, nucleic acid encoding SEQ ID NO:2, and nucleic acid encoding SEQ ID NO:11.

If Group I is elected, the Office requires an election of a single disclosed species from each of Genus 1 and Genus 2.

In Group II there is one genus containing the following species:

- SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:11

If Group II is elected, the Office requires an election of a single disclosed species

Request for Reconsideration under 37 C.F.R. §1.143

Applicant respectfully requests reconsideration and modification of this restriction and species election requirement. The presently claimed inventions of Groups I and II are drawn to methods of aiding in the diagnosis of, or susceptibility to a neoplastic condition of an animal cell or tissue comprising determining the amount of expression of an eIF3 protein in a test sample isolated from said cell or tissue.

The Office acknowledges that claims 1, 7 and 14 are generic to Groups I and II. Claim 14 contains a Markush grouping comprising specifically defined sources of the test sample, *i.e.,* ovary, breast, prostate, lung, pancreas, gastrointestine, and blood. The Office has indicated that the above-listed members of the (claim 14) Markush grouping are the Genus 1 species contained in the invention claims of Group I. While claim 14 is also generic to Group II, the Office has not required such species election for the invention claims of Group II. It is submitted that the "tissue source" of a sample in methods for diagnosing neoplastic conditions or determining susceptibility to neoplastic conditions is not a burden, and does not require a separate search for each individual species member. Reconsideration and modification of this restriction and species election requirement is respectfully requested.

The Office has recently instituted a policy directed to improving restriction practice within TC 1600 as stated by the recent publication of the TC1600 Restriction Practice Action Plan (press release on October 6, 2003). This policy emphasizes the importance of the quality and consistency of restriction practice and recognizes the need for improvements in this complex technology unit.

As stated by the Office, there are two criteria for a proper requirement for restriction between patentably distinct inventions, MPEP 803. First, the inventions must be independent or distinct. Second, there must be a serious burden on the Examiner if restriction is required. The Examiner must examine the subject application on the merits even if it includes claims to distinct inventions if such an examination can be made without serious burden. Applicant asserts that the search of claims 1-9 does not comprise a serious burden.

Claims 5 and 6 of Group I each contain a Markush grouping comprising 2 specifically defined nucleic acid sequences. Claims 12 and 17 of Group II contain a Markush grouping comprising 6 specifically defined peptide sequences. According to MPEP § 803.02. the Examiner must examine all members of the Markush group in the claims on the merits even if they are directed to independent and distinct inventions, if the examination can be made without serious burden.

> "If the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions." MPEP § 803.02.

Applicant submits that these claims can be searched without serious burden.

First, the Office is capable of readily performing sequence searches of peptide sequences. The peptide sequences present in the instant claims are relatively uncomplicated. Many sequences have similar characteristics such as shared anchor residues. Additionally, Applicant has provided a sequence listing for the instant sequences. These factors indicate that an examination of the peptide sequences contained in the Markush group of the instant claims can be reasonably performed.

Second, Applicant notes that chemical cases with Markush groups, which often contain complicated chemical R group structures, are routinely searched without

restriction. The instant claims do not contain complicated R groups. Rather, a search of the instant peptide sequences constitutes straight sequence searching. The different standard that the Office appears to be applying for Markush groups containing peptide structures is unsupported.

Third, the Office operates under a policy wherein 10 nucleotide sequences constitute a reasonable number for examination purposes, MPEP § 803.04. This allows for the examination of up to ten independent and distinct sequences in a single application without restriction. There are no distinct limitations on nucleotide sequence length and complexity in this policy, suggesting that potentially long or complicated sequences are considered reasonable to search. The Office also provides guidelines for the search of combinations of 10 or more individual sequences where they are claimed.

As stated in MPEP § 803.04:

> "If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth... More specifically, the combination will be searched until one nucleotide is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed.

It would appear that the Office readily recognizes that a search of a combination of 10 or more sequences does constitute a reasonable search and examination burden. Indeed, the pertinent policy behind this decision in § 803.04:

> "Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application."

The invention claimed in Group I contains less than 10 nucleotide sequences and the above-policy does apply to the search of all the sequences claimed therein. Applicant further submits that it is reasonable to apply a similar policy to the search of Group II

inventions containing only 6 peptide sequences, whose searches are performed in a similar manner.

Provisional election under 37 C.F.R. §1.143

Pursuant to 37 C.F.R. §1.143, Applicant's undersigned attorney hereby elects with traverse, the invention of Group I, Claims 2-6, 13, 15, 19-21 are drawn to a method of aiding in the diagnosis of the neoplastic conditions, classified in class 435, subclass 6; and Genus 1 species: ovary and Genus 2 species: nucleic acid encoding SEQ ID NO: 11, reading on claims 5 and 6 of Group I.

CONCLUSION

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

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Date

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